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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,150	CHILDERS ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 7,208,092. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent claim similar subject matter including a system for peritoneal dialysis, a catheter with inflow and outflow lumen, a fluid circuit, a cycler, a cleaning device, a reservoir, etc.

Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/623316. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the

above application claim similar subject matter including continuous flow peritoneal dialysis, recirculating dialysate fluid through a closed loop, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen

(Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit including: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid circuit; at least one of a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop via the actions of the valves), and a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than

the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 2, Roberts discloses that the feed rate and the discharge rate are less than the circulation rate (paragraph 2, col. 1, page 377 discloses using inflow and outflow rates of 30 ml/min while using a higher circulation rate. Also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using a

circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged).

In reference to claim 5, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300: Also, paragraph 2,. col. 1, page 377 discloses using a rate of 200 ml/min).

In reference to claim 6, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 7, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 8, Roberts discloses that the dialysate is infused into the peritoneal cavity of the patient and an additional volume of the dialysate is subsequently and continuously fed into the fluid circuit during treatment (paragraph 2, col. 1, page 377).

In reference to claim 9, Roberts discloses that the initial volume of the dialysate is circulated along the fluid loop during an initial treatment period without the continuous feed of the additional volume of the dialysate into the fluid loop and the continuous discharge of dialysate from the fluid loop (paragraph 2, col. 1, page 377).

In reference to claim 10, Treu discloses the chamber (88) allowing the fluid loop to accommodate a variable increase in the dialysate during treatment (Fig. 2).

In reference to claim 11, Roberts discloses that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

In reference to claim 12, Roberts discloses that the feed rate and the discharge rate are alternatively varied to create tidal CFPD (paragraph 2, col. 1, page 377).

Claims 13, 14, 16-18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit consisting of: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated) via only a single loop of the fluid loop (Fig. 2 discloses that this can be accomplished by passing through the loop 10 once); a supply of dialysate; a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop

via the actions of the valves); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to

the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 14, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 16, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min):

In reference to claim 17, Roberts discloses that the chamber is capable of mixing and heating the dialysate (Fig. 7 and 12, specifically Fig. 12 discloses a heater).

In reference to claim 18, Treu discloses that the chamber (88) is coupled to the fluid loop via a fluid supply path (Fig. 2 discloses that the chamber is coupled to the fluid supply path as the fluid enters 88 after it passes through 78).

In reference to claim 20, Treu discloses that the chamber is directly coupled to the fluid loop (Fig. 2 discloses that 88 is directly coupled to the fluid loop 10).

In reference to claim 22, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 23, Treu discloses that the chamber can be adapted to accommodate a variable increase in the dialysate during treatment (Fig. 2, 88 allows a variable increase which is monitored by 90).

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit including: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid loop; a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device

and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates

at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 25, Treu discloses that the fluid loop is coupled to the supply of dialysate, the cleaning fluid path and the discharge fluid path via a cycler (12).

In reference to claim 26, Treu discloses that the cycler includes a fluid circuit coupled to a pumping mechanism and a plurality of valves such that the cycler is capable of automatically controlling the flow of dialysate into and out of the fluid loop during treatment (Fig. 2 discloses valves 80 and 92).

In reference to claims, 27 and 28, Roberts discloses that the cleaning device contains a sorbent material (Fig. 6 discloses using a sorbent cartridge) capable of non\-selective removal of solutes from the dialysate prior to reuse and that the sorbent material is carbon (col. 1, paragraph 3, line 1).

In reference to claim 29, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 30, Treu discloses a chamber (88) coupled to the fluid loop that is capable of accommodating for a variable increase in dialysate volume during treatment (the increase in monitored by 90).

Claim 3, 4, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate

Regeneration"). Roberts discloses the device substantially as claimed .including the feed rate and the discharge rates being lower than the circulation rate (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377). Roberts however, does not disclose that the feed and discharge rates are maintained equally at a rate that is either one-half or one-third of the circulation rate, such that the dialysate circulates either two or three times along the fluid loop. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Roberts such that the feed and discharge rates are either one-half or one-third the circulation rate, because it is a mere manipulation or arithmetic in order to derive a circulation of two or three times around the loop, and because it has been held that discovering an optimum value of a result effective Variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments, see pages 7-12, filed 11/30/2007, with respect to the references used in the rejection, have been fully considered and are persuasive. The rejection of claims 1-30 has been withdrawn.

Upon reviewing previously used references, however, the examiner believes that the Treu reference is still applicable as Applicant argued in their response filed 10/31/2006 that Treu discloses more than one fluid loop. However, as presented above and as seen in Figs. 1 and 2, Treu discloses only one fluid loop through which the dialysate is circulated through. Any other possible fluid paths, such as the path leading to 44, which applicant may argue is a loop, is not a loop as defined by applicant's claims, as these are not paths through which the dialysate passes through and is circulated. The path leading to 44, for example, is a path for regeneration solution, not for dialysate. Therefore Treu does in fact teach one fluid loop for the circulation of the dialysate. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. C. S./
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767